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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,941	10/14/2003	Chin-Ming Chang	17501CON1 (AP)	7685

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EXAMINER

KWON, BRIAN YONG S

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuksel et al. (Ophthalmologica, 1999, 213(4), 228-233).

The claims read on a method of treating glaucoma or ocular hypertension comprises topically administering a therapeutically effective amount of a single composition comprising an effective amount of brimonidine and an effective amount of timolol in a pharmaceutically acceptable carrier thereof, to the affected eye. Further limitations include “the concentration of brimonidine is from 0.01% to 0.5% by weight and the concentration of timolol is 0.1% to 1.0% by weight” (claim 27); “the concentration of brimonidine is over 0.1% to about 0.2% by weight and the concentration of timolol is over 0.25% to about 0.5% by weight” (claims 28); “the concentration of brimonidine is 0.2% to about 0.5% by weight and the concentration of timolol is 0.5% to about 1.0% by weight” (claim 29); and “the concentration of brimonidine is about 0.2% by weight and the concentration of timolol is about 0.5% timolol by weight” (claim 30).

Yuksel teaches use of 0.2% brimonidine in combination with 0.5% timolol for treating glaucoma by lowering intraocular pressure (abstract; Figs. 1-2; Tables 2-3; and page 232, column 1, para. 1), wherein said brimonidine is administered separately 5 minutes apart from timolol. Yusel also teach that the combination therapy would provide significantly greater efficacy of the drugs without clinical symptoms or adverse effects.

The teaching of Yuksel differs from the claimed invention in (i) the administration of brimonidine and timolol in a single composition and (ii) the specific dosage range of active ingredients, namely brimondine and timolol.

However, such determination of formulating two compositions each of which is taught by prior art to be useful for same purpose in a single container is well within the skill of artisan. Above references in combination make clear that brimonidine and timolol have been individually used for the treatment of glaucoma. It is obvious to combine two compositions each of which is

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taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. One having ordinary skill in the art would have expected that the administration of brimonidine and timolol in a single composition would be advantageous in accommodating patient's preference and needs where the compliance could be improved by delivering the drugs in single application. One having ordinary skill in the art would have been motivated to modify the teaching of Yuksel to administer brimonidine and timolol in a single composition such that therapeutic outcome could be greatly enhanced by delivering the active ingredients in a convenient single composition. Determination of the appropriate dosage for treatment involving each of the above mentioned formulations would have been obvious to those of ordinary skill in the art, and the skilled artisan would have been arrived at the claimed without undue experimentation, especially in light of the pharmacokinetics of each drug (i.e., half-life, onset of action, duration of drug).

Regardless of the different mode of administering timolol and brimonidine in a single composition or combination but in a separate composition, the claimed method would have been *prima facie* obvious to a person skill in the art, at the time of the claimed the invention was made, because the prior art teaches the combination use of timolol and brimonidine for the treatment of glaucoma by lowering IOP.

The above references in combination make clear that the combination of brimonidine and timolol would provide added advantage in reducing adverse effects when they are used together for the treatment of glaucoma by lowering intraocular pressure.

One having ordinary skill in the art would have been motivated at the time of the invention was made to combine these references and make the modification because they are

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drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 26-30 are provisionally rejected under the judicially created doctrine of double patenting over claims 54-57 of copending Application No.10/126,790, which has been allowed, but not yet patented. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both the instantly claimed subject matter and the copending application are drawn to a method for treating glaucoma or ocular hypertension administering a composition comprising brimonidine and timolol in a pharmaceutically acceptable carrier wherein the concentration of brimonidine and timolol in the instant claims overlaps with the concentration of brimonidine and timolol in the copending claims.

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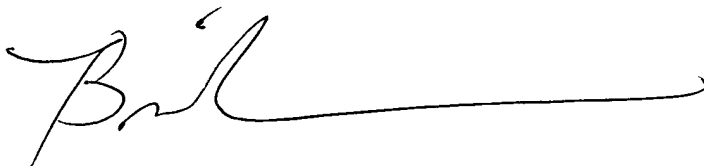
Conclusion

3. No Claim is allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to read 'Brian Kwon', followed by a long horizontal line extending to the right.